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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/121,211      | 07/23/1998  | TOSHIMICHI SHINOHARA | B0801/7116          | 3070             |

7590 08/13/2002  
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EXAMINER

ROMEO, DAVID S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 08/13/2002

*rr*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/121,211

Applicant(s)

SHINOHARA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22,26,29,31,34,35,44,45,47,49,52,55,56,58,61,64 and 70 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-11 and 26 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-22,29,31,34,35,44,45,47,49,52,55,56,58,61,64 and 70.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-22,26,29,31,34,35,44,45,47,49,52,55,56,58,61,64 and 70.

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**DETAILED ACTION**

The amendment filed March 5, 2002 (Paper No. 21) has been entered. Claims 1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70 are pending. Claims 12-22, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, 70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 9. Claims 1-11, 26 are being examined. Claim 26 is being examined only to the extent that it reads upon an agent that is a nucleic acid molecule. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Maintained Formal Matters, Objections, and/or Rejections:*****Claim Rejections - 35 USC § 112***

Claims 1, 8, 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for a nucleic acid molecule which hybridizes to SEQ ID NO:1 and encode a polypeptide that stimulates the growth of lens epithelial cells. The grounds of this rejection are set forth in the last Office action (Paper No. 20) at paragraph 4. Applicants did not address this rejection in their response filed March 5, 2002 (Paper No. 21). The rejection of record is applied to claim 26 because claim 26 encompasses the nucleic acid molecule of claim 1.

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Claims 4-7, 9, 11, 26 are rejected under 35 USC 112, second paragraph, over the recitation of "unique". See the last Office action (Paper No. 20) at paragraph 7i. Applicants argue that a unique fragment acts as signature and those skilled in the art are well versed in methods for selecting such sequences. Applicants arguments have been fully considered but they are not persuasive. According to the present specification the unique fragment must contain a nucleotide sequence other than the exact sequences of those in GenBank or fragments thereof. The difference may be an addition, deletion or substitution or may be a sequence wholly separate from a GenBank sequence. Firstly, revisions or updates to GenBank entries can be made at any time. The interpretation of a claim that whose interpretation is dependent upon a GenBank entry is dependent upon the particular revision, update or release date of that particular entry. The metes and bounds of the claim(s) are not clearly set forth.

**New formal matters, objections, and/or rejections:**

***Claim Rejections - 35 USC § 112***

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to a first nucleic acid molecule that hybridizes to a second nucleic acid molecule that hybridizes to SEQ ID NO: 1. This is a genus claim. There are no limitations to the hybridization conditions under which the first nucleic acid molecule hybridizes to the second nucleic acid molecule and the hybridization conditions under which the first nucleic acid molecule hybridizes to the second nucleic acid molecule encompasses non-

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specific hybridization. The specification, claim, and hybridization conditions under which the first nucleic acid molecule hybridizes to the second nucleic acid molecule do not indicate what distinguishing attributes shared by the members of the genus. The specification, claim and hybridization conditions under which the first nucleic acid molecule hybridizes to the second nucleic acid molecule do not place any limit on the number of nucleotide substitutions, deletions, insertions and/or additions that may be made. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1, nucleic acid molecules that differ from SEQ ID NO: 1 in codon sequence due to the degeneracy of the genetic code, complements of SEQ ID NO: 1, and complements of nucleic acid molecules that differ from SEQ ID NO: 1 in codon sequence due to the degeneracy of the genetic code alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the limitations of claim 7, as a whole, cannot be found in the specification or claims as originally filed and the introduction of such limitations, as a whole, raises the issue of new matter. Support for the limitation "at least 75% amino acid identity" cannot be found in the specification or claims as originally filed and the introduction of such a limitation raises the issue of new matter.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to or encompasses a fragment of the polypeptide thereof that binds a human antibody. The present specification teaches a polypeptide that binds an antibody contained in sera of ARC patients (page 45, Example 1). However, the claims are not limited to an antibody contained in sera of ARC patients, wherein the antibody binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 2. The claims are directed to or encompass a polypeptide or a fragment of the polypeptide thereof which binds any and all human antibodies. The claims are genus claims. The specification fails to describe a polypeptide or a fragment of the polypeptide thereof that binds a human antibody other than an antibody contained in sera of ARC patients. While it may be obvious to the skilled artisan to attempt to isolate other human antibodies that bind a polypeptide or a fragment of the polypeptide thereof, the written description requirement is not satisfied by that which is obvious over which is disclosed, only that which is disclosed.

### *Conclusion*

Claim 4 is directed to an isolated nucleic acid molecule that is a unique fragment of SEQ ID NO: 1 wherein the fragment is between 20 and 3360 nucleotides in length or to an isolated nucleic acid molecule that is the complement of a unique fragment of SEQ ID NO: 1 wherein the fragment is between 20 and 3360 nucleotides in length. Therefor the isolated nucleic acid molecule to which claim 4 is directed consist of either a unique fragment of SEQ ID NO: 1 wherein the fragment is between 20 and 3360 nucleotides in length or the complement of a unique fragment of SEQ ID NO: 1. The unique fragment must also include, i.e., comprise, a sequence of contiguous nucleotides which is not identical to either SEQ ID NO: 21 or the complement of SEQ ID NO: 21. Therefore the additional sequence, which the unique fragment must also comprise, consist of a fragment of SEQ ID NO: 1. The claimed nucleic acid molecule in claim 4 consist of one contiguous fragment of SEQ ID NO: 1 that is 20 to 3360 nucleotides long. Claim 7 is directed to the isolated nucleic acid molecule of claim 4, wherein the isolated nucleic acid molecule of claim 7 encodes a polypeptide, wherein the polypeptide shares at least 75% identity to SEQ ID NO: 2. Since the isolated nucleic acid molecule of claim 4 consist of one contiguous fragment of SEQ ID NO: 1, then the polypeptide encoded by the isolated nucleic acid molecule of claim 7 can only be interpreted to encompass a polypeptide consisting of 397 (75% of 530 amino acids) contiguous amino acids of SEQ ID NO: 2.

Claims 2, 3 are objected to as being dependent upon a rejected base claim.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.



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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
AUGUST 11, 2002